Application/Control Number: 10/582,445 Page 2

Art Unit: 3761

DETAILED ACTION

Claim Language Interpretation

4. The claim terminology is interpreted in light of the definitions on page 4, line 25-page 5, line 1 (<u>It is noted that such does not require wearing entirely inside or outside</u>) and page 8, lines 18-20. Any other claim language not specifically defined has been interpreted in view of the usual and common meaning of such, e.g. the dictionary definition.

Claim Rejections - 35 USC § 103

- The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
- Claims 1-3, 7-8, 10 and 12-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Llovd EP '039 in view of Wilson III. '779.

Claim 1: See Claim Language Interpretation section supra, hereinafter also referred to as CLI, and '039 at the Figures, esp. 1-4B, page 27, line 8-page 31, last line, page 4, lines 3-11, page 15, lines 16-27, page 10, lines 15-20, the paragraph bridging pages 14-15, page 15, first full paragraph, page 16, lines 1-17, page 17, lines 1-6 and 14-22, page 18, line 1-page 19, line 14, page 20, line 1-page 21, line 9, and page 22, line 19-page 24, last line, i.e. '039 teaches a sanitary product for insertion into a human vagina which includes an internally worn absorbent plug, e.g., at least a portion of 11, and an externally worn absorbent pad, e.g. 6, joined to one another by a sheath 2, 3

Art Unit: 3761

that opens through the pad, see, e.g., Figures, esp. 2A and/or page 21, lines 5-9, such that a wearer's finger can be received in the sheath to assist insertion, see, e.g., page 15, lines 1-7 and 11-15 or page 29, lines 13-16. Claim 1 now also requires the sheath be elastic in only a circumferential direction which allows for radial expansion. While '039 at, e.g., the paragraph bridging pages 14-15, the first full paragraph on page 15. page 16, lines 8-10 and page 17, lines 13-17 teaches the sheath of various flexible. e.g., resilient, knit or elastic materials, and capable of expansion diametrically/circumferentially/in a radial direction to receive a finger, i.e. a body part, for digital insertion of the product into the vagina, it does not explicitly disclose the sheath is elastic in only a circumferential direction, i.e. is capable of expansion and retraction in only the circumferential direction. However, see '779 at the abstract, the Figures, col. 1, lines 8-13, 43-46, col. 5, lines 10-19, the Summary of the Invention section, col. 7, lines 38-col. 8, line 3, col. 10, lines 20-32, col. 12, lines 28-43 the paragraph bridging cols. 14-15, the claims, esp. note the preambles, i.e. teaches not only a sheath of various flexible, e.g., resilient, knit or elastic, materials which is capable of expansion diametrically/circumferentially/in a radial direction to receive a body part, but also which is elastic in only a circumferential direction, i.e. is capable of expansion and retraction in only the circumferential direction, in order to enhance retention. Therefore, to make the sheath capable of expansion diametrically/circumferentially/in a radial direction to receive a finger, i.e. a body part, of '039 a sheath elastic in only a circumferential direction which allows for radial expansion instead, if not already, would either be obvious, see In re Siebentritt, 54 CCPA 1083, i.e. two equivalents are interchangeable

Art Unit: 3761

for the desired function, express suggestion of desirability not needed to render such substitution obvious, i.e. here the equivalents are interchangeable for the desired function of providing expansion diametrically/circumferentially/in a radial direction to receive a body part, i.e. finger, and/or would be obvious to one of ordinary skill in the art in view of the teachings of '779 due to the recognition that such would not only provide a sheath capable of expansion diametrically/circumferentially/in a radial direction to receive a finger but also provide retention thereon which would enhance the efficacy of digital insertion and the desire of such expansion and insertion by '039.

Claim 2: See, e.g., page 17, lines 1-6 and page 19, lines 1-11, i.e. the sheath is liquid impermeable in a direction from the outside of the sheath to the inside of the sheath.

Claim 3: See discussion of claims 1-2, i.e. the sheath comprises tube of liquid impermeable material.

Claim 7: See page 20, lines 7-8 and page 24, lines 12-15, i.e. the sheath comprises a tube of absorbent material.

Claim 8: See overlapping tubular portions of 12, in Figures 1-1A, 2-2A, 3-3A, 4-4B, page 17, lines 1-6, page 18, lines 12-17, page 20, lines 3-8, page 24, last paragraph, i.e. the sheath comprises a tube of liquid impermeable material inside a tube of absorbent material.

Claim 10: See Figure 2B adjacent the arrow from 2 or page 24, last paragraph, i.e. the sheath has a smaller diameter than that of the plug.

Art Unit: 3761

Claim 12: See Figure 1B and page 15, lines 16-27, i.e. the sheath extends for substantially 2.5 cm between an end of the plug and a surface of the pad closest to the plug with "sufficient specificity", see MPEP 2131.03.

Claims 13-14: See Figures, i.e. the product further comprises a cord 7 attached to the plug to assist removal of the plug from the vagina which cord extends along the inside of the sheath.

 Claims 1, 3-6 and 27 – 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kaysersberg '405 in view of Wilson III, '779

Claim 1: See Claim Language Interpretation section supra, hereinafter also referred to as CLI, and '405 at the Figures, esp. 3-4 and 6, the English abstract, see the full English translation, esp. the translation at page 16, second full paragraph, page 10, first full paragraph, page 16, third full paragraph, page 14, second full paragraph and the paragraph bridging pages 14, i.e. '405 teaches a sanitary product for insertion into a human vagina which includes an internally worn absorbent plug, e.g., at least a portion of 44, 444, and an externally worn absorbent pad, e.g. 2, joined to one another by a sheath 66 that opens through the pad, see, e.g., Figures, such that a wearer's finger can be received in the sheath to assist insertion, see, e.g., the second full paragraph on page 16. Claim 1 now also requires the sheath be elastic in only a circumferential direction which allows for radial expansion. While '405 at, e.g., page 13, second and third full paragraphs and the paragraph bridging pages 13-14 teaches the sheath includes an elastic, deformable or equivalent means capable of receiving a finger, i.e. a body part, for digital insertion of the product into the vagina, it does not explicitly

Art Unit: 3761

disclose the sheath is elastic in only a circumferential direction, i.e. is capable of expansion and retraction in only the circumferential direction. However, see '779 at the abstract, the Figures, col. 1, lines 8-13 and 43-46, col. 5, lines 10-19, the Summary of the Invention section, col. 7, lines 38-col. 8, line 3, col. 10, lines 20-32, col. 12, lines 28-43, the paragraph bridging cols. 14-15, the claims, esp. note the preambles, i.e. teaches not only a sheath which has an elastic, deformable or equivalent means capable of receiving a body part but such means being elastic in only a circumferential direction, i.e. capable of expansion and retraction in only the circumferential direction, in order to enhance retention. Therefore to make the elastic, deformable or equivalent means of '405 an elastic/deformable structure as taught by '779, if not already, would either be obvious, see In re Siebentritt, 54 CCPA 1083, i.e. two equivalents are interchangeable for the desired function, express suggestion of desirability not needed to render such substitution obvious, i.e. here the equivalents are interchangeable for the desired function of providing deformable/elastic means to receive a body part, i.e. finger, and/or would be obvious to one of ordinary skill in the art in view of the teachings of '779 due to the recognition that such would not only provide a sheath/means thereof capable of expansion diametrically/circumferentially/in a radial direction to receive a finger but also providing retention thereon which would enhance the efficacy of digital insertion and the desire of such expansion and insertion by '405.

Claim 3: See cited portions in discussion of claim 1, i.e. the sheath 66 comprises a tube of liquid impermeable material.

Art Unit: 3761

Claims 4-5: See cited portions in discussion of claim 1, i.e. the pad 2 comprises an absorbent layer 7 and a liquid impermeable backing sheet 99 and the backing sheet is integral with the liquid impermeable material of the sheath, see Figure 3.

Claim 6: The sheath passes liquid along its length from the plug to the pad, see English abstract.

Claim 27: The pad is configured to be wearable only externally to the vagina of the wearer, see figure 1 of Kaysersberg.

Claim 28: The plug is connected to one end of the sheath and the pad is connected to the other end of the sheath, see figures 2 – 3 of Kaysersberg.

8. Claims 15 and 19-20 are rejected under 35 U.S.C. 103(a) as being unpatentable Lloyd EP '039 and Wilson III, '779 as applied to claim 1 supra, and further in view of Phelps '234, and Denkinger '372.

Claims 15 and 19-20: See the paragraph bridging pages 14-15 and MPEP 2131.03, i.e. the diameter of the plug is 2 cm or less, 1.5 cm or less or 1.5 cm, respectively, with "sufficient specificity". Note also page 12, lines 7-9 of the instant specification. These claims further require the plug be substantially 4 cm in length or less, substantially 3.5 cm in length or less or substantially 3.5 cm in length, respectively. While '039 suggests such lengths, e.g. see page 15, lines 24-27 and the Figures, '039 does not explicitly teach such. However, note page 12, lines 7-11 of the instant specification, as well as '234 at col. 2, lines 55-58 and '372 at col. 1, lines 64-65 and col. 3, lines 12-15, i.e. the prior art desires the same properties/combination of properties as the instant application, i.e. a portion which is absorbent and sized for wear internally in

Art Unit: 3761

the vagina as well as length/size being a result effective variable or specific sizes within the claimed ranges. Note also MPEP 2141.05. Therefore, even if the prior art does not include the exact length, the general conditions of the claim are disclosed thereby and it is not inventive, i.e. it would be obvious to one of ordinary skill in the art, to discover the optimum or workable ranges, i.e. Applicant's ranges, by routine experimentation, In re Aller, 105 USPQ 233 (CCPA 1955).

 Claims 21-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over are rejected under 35 U.S.C. 103(a) over Kaysersberg '405 and Wilson III, '779 as applied to claim 1 supra, and further in view of Ohba PCT'611 and Denkinger '372.

Claim 21: This claim requires an external portion, i.e. pad, have the shape of a flat ellipse with one end wider than the other. While page 11, lines 25-26 of '405 teach the external absorbent portion may be rectangular, oblong, sandglass or other shape it does not teach the claimed specific shape. However, see '611 at page 6, lines 10-13 and Figures 3-7 of '372, esp. Figure 7, i.e. interchangeability of shapes of external absorbent portions similar to '405 for those claimed, i.e. ellipsis with different sized ends. To make the shape of '405 the claimed shape instead would be obvious to one of ordinary skill in the art in view of the interchangeability as taught by '611 and '372.

Claims 22-23: These claims require the pad be substantially 6.5cm long and 5.5cm wide or substantially 0.5cm thick, respectively, which '405 does not teach.

However, see '611 at page 6, lines 18-30 and '372 at col. 3, lines 12-18 as well as page 13, lines 7-13 of the instant specification, i.e. the prior art desires the same properties/combination of properties as the instant application, i.e. a portion which is

Art Unit: 3761

absorbent and sized for comfortable wear externally as well as length/width/caliper/size being result effective variables and/or specific sizes within the claimed ranges. Note also MPEP 2141.05. Therefore, at the very least the general conditions of the claim are disclosed thereby and it is not inventive, i.e. it would be obvious to one of ordinary skill in the art, to discover the optimum or workable ranges, i.e. Applicant's ranges, by routine experimentation, In re Aller, 105 USPQ 233 (CCPA 1955).

Double Patenting

- 10. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
- 11. Claims 1-8, 10, 12-15, 19-23 and 27 28 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-28 of copending Application No. 11/920481. Although the conflicting claims are not identical, they are not patentably distinct from each other. Since there was no administrative delay, the one way In re Vogel test applies, i.e. are the claims of the instant application obvious in view of the other application claims? The answer is yes. Claim 1 of the instant application is broader with regard to some aspects and narrower with regard to other aspects of the claims of the other application. With regard to the broader aspects (e.g. the instant application does not require a line of weakness, see claim 1 in the other application), once an applicant has received a patent for a species or more specific embodiment, he is not entitled to a patent for the generic or broader invention. This is because the more specific anticipates the broader, i.e. the patented

Art Unit: 3761

claim anticipates the application claim. See In re Goodman, supra. With regard to the narrower aspects (e.g. the instant application claim 1 requires a sheath which is elastic in only a circumferential direction which allows for radial expansion), note claims, e.g., 18 and 17 in the other application as originally filed and as now amended. To make a sheath as claimed in the other application, e.g., claim 18, which is capable of receiving a finger also resiliently expandable in a radial direction as claimed in claim 17 of the other application would be obvious to one of ordinary skill in the art in view of the recognition that such provides the sheath with the capability of receiving a finger as desired.

This is a <u>provisional</u> obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Response to Arguments

12. Applicant's remarks filed August 9, 2011 have been carefully considered but are deemed either moot in that the issue discussed has not been reraised or not persuasive for the reasons discussed supra. Specifically, Applicant argues that the piston 6 of Lloyd is not an absorbent pad. The examiner disagrees and refers to the rejection of claim 1, see at least page 20, lines 14 - 20. The applicant is reminded that the arguments with regard to each singular reference is not commensurate with the grounds of rejection based upon a combination of references, not any one singular reference. Also, Applicant's remarks with regard to the prior art references is narrower than the claim language and/or the teachings of the prior art. The arguments with

Art Unit: 3761

respect to Wilson are not persuasive as the supposed implicit disclosure is not necessarily a certainty and in view of the fact that the Office Action provides an obviousness statement with respect to the elasticity of the materials. The applicant does not dispute the obviousness rejection and therefore the rejection is maintained.

In response to applicant's argument that Wilson, III is nonanalogous art, it has been held that a prior art reference must either be in the field of applicant's endeavor or, if not, then be reasonably pertinent to the particular problem with which the applicant was concerned, in order to be relied upon as a basis for rejection of the claimed invention. See *In re Oetiker*, 977 F.2d 1443, 24 USPQ2d 1443 (Fed. Cir. 1992). In this case, all of the cited prior art references are directed to personal care articles and would have reasonably been considered by one of ordinary skill in the art.

Applicant's remarks with regard to Kaysersberg are also narrower than the claim language, i.e. "joined" includes either director indirect joining and/or the claim does not require joining of the plug and pad only by the sheath, and/or the teachings of Kayserberg, see the entire reference, esp., e.g., the cited portions and Figures, i.e. at the very least the sheath, e.g. 66, 666, indirectly joins the pad, e.g., pad portion 99, 999, to the plug, e.g., 44, 444.

Applicant's remarks on page 5 regarding the double patenting issues have been noted.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

Art Unit: 3761

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michele M. Kidwell whose telephone number is (571)272-4935. The examiner can normally be reached on Monday thru Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tatyana Zalukaeva can be reached on 571-272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Application/Control Number: 10/582,445 Page 13

Art Unit: 3761

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/MICHELE M KIDWELL/ Primary Examiner, Art Unit 3761